


SAFETY DATA SHEET

Lidocaine Hydrochloride Oral Topical Solution, USP (Viscous) 2%

1. IDENTIFICATION

Product Identifier:	Lidocaine Hydrochloride Oral Topical Solution, USP (Viscous) 2%
Synonyms:	Acetamide, 2-(diethylamino)-N-(2,6-dimethylphenyl)-, monohydrochloride, monohydrate
National Drug Code (NDC):	50383-775-04 50383-775-17
Recommended Use:	Pharmaceutical. Lidocaine Hydrochloride Oral Topical Solution, USP (Viscous) 2% is indicated for the production of topical anesthesia of irritated or inflamed mucous membranes of the mouth and pharynx. It is also useful for reducing gagging during the taking of X-ray pictures and dental impressions.
Company:	Akorn, Inc. 1925 West Field Court, Suite 300 Lake Forest, Illinois 60045
Contact Telephone:	1-800-932-5676
E mail:	customer.service@akorn.com
Emergency Phone Number:	CHEMTREC 1-800-424-9300 (U.S. and Canada)

2. HAZARD(S) IDENTIFICATION

Physical Hazards:	Not classified.	
Health Hazards:	Specific Target Organ Toxicity – Repeated Exposure	Category 2
Symbol(s):		
Signal Word:	Warning.	
Hazard Statement(s):	H373 May cause damage to organs through prolonged or repeated exposure.	
Precautionary Statement(s):	P260 Do not breathe vapor or spray. P264 Wash hands thoroughly after handling. P314 Get medical attention if you feel unwell.	

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P305 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
 +
 P351
 +
 P338

P337 If eye irritation persists: Get medical attention.
 +
 P313

P501 Dispose of contents/container in accordance with local/regional/national/international regulations.

Hazards Not Otherwise Classified: Not classifiable.

Supplementary Information: None.

3. COMPOSITION / INFORMATION ON INGREDIENTS

Ingredient	Synonyms	CAS Number	Chemical Formula	Molecular Weight	Percentage
Lidocaine Hydrochloride	Acetamide, 2-(diethylamino)-N-(2,6-dimethylphenyl)-, monohydrochloride, monohydrate	6108-05-0	$C_{14}H_{22}N_2O$	234.34	2%

The formula also contains the following inactive ingredients: Carboxymethylcellulose Sodium, Methylparaben, Natural Orange Flavor, Propylparaben, Purified Water, and Saccharin Sodium. The pH is adjusted to 5.0 to 7.0 by means of Hydrochloric Acid and/or Sodium Hydroxide.

4. FIRST AID MEASURES

Ingestion: If a person vomits place them in the recovery position so that vomit will not reenter the mouth and throat. Rinse mouth with water. If swallowed, seek medical advice immediately and show the container or label. Treat symptomatically and supportively. Ensure that medical personnel are aware of the material(s) involved and take precautions to protect themselves.

Eye Contact: Remove from source of exposure. Flush with copious amounts of water for at least 15 minutes. If irritation persists or signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary. Ensure that medical personnel are aware of the material(s) involved and are aware of precautions to protect themselves.

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Skin Contact:	Remove from source of exposure. Remove and isolate contaminated clothing and shoes. Flush with copious amounts of water for at least 20 minutes. Use soap. If irritation persists or signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary. Ensure that medical personnel are aware of the material(s) involved and are aware of precautions to protect themselves.
Inhalation:	Remove from source of exposure. Move individual(s) to fresh air. Give artificial respiration if individual(s) are not breathing and call emergency medical service. If signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary. Ensure that medical personnel are aware of the material(s) involved and are aware of precautions to protect themselves.
Protection of First-Aiders:	Use personal protective equipment (see section 8).
Signs and Symptoms:	Inadvertent contact with this product may cause irritation, followed by numbness. Ingestion may cause numbness of the tongue and anesthetic effects on the stomach. In clinical use, this product produces numbness when injected. Systemic absorption can produce central nervous system (CNS) stimulation and/or CNS depression. CNS depression may progress to coma and cardio-respiratory arrest. Signs of cardiovascular toxicity may include changes in cardiac conduction, excitability, refractoriness, contractility, and peripheral vascular resistance. Toxic blood levels may cause atrioventricular block, ventricular arrhythmias, cardiac arrest, and sometimes death. In addition, decreased cardiac output and arterial blood pressure may occur. Allergic-type reactions are rare but may occur due to sensitivity to the local anesthetic or to other formulation ingredients. These reactions are characterized by signs such as urticaria, pruritus, erythema, angioneurotic edema (including laryngeal edema), tachycardia, sneezing, nausea, vomiting, dizziness, syncope, excessive sweating, elevated temperature, and possibly, anaphylactic-like symptoms (including severe hypotension). Cross sensitivity with other amide-type local anesthetics has been reported.
Medical Conditions Aggravated by Exposure:	As with all pharmaceuticals, hypersensitivity is possible.
Notes to Physician:	Treat supportively and symptomatically. Excessive dosage, or short intervals between doses, can result in high plasma levels and serious adverse effects. Patients should be instructed to strictly adhere to the recommended dosage and administration guidelines as set forth in the package insert. The management of serious adverse reactions may require the use of

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resuscitative equipment, oxygen and other resuscitative drugs.

5. FIREFIGHTING MEASURES

Suitable Extinguishing Media: Use water, carbon dioxide, dry chemical or foam as necessary.

Unsuitable Extinguishing Media: Not determined.

Specific Hazards Arising from the Chemical

Hazardous Combustion Products: None.

Other Specific Hazards: Closed containers may explode from the heat of fire.

Special Protective Equipment and Precautions for Firefighters: Wear self-contained breathing apparatus and full and protective gear.

6. ACCIDENTAL RELEASE MEASURES

Personal Precautions: Use personal protective equipment recommended in Section 8 of this document and isolate the hazard area.

Personal Protective Equipment: For personal protection see section 8.

Methods for Cleaning Up: Absorb with inert material. Recover product and place in an appropriate container for disposal in accordance with local, state and federal regulations.

Environmental Precautions: Contain material and prevent release to basements, confined spaces, waterways or soil.

Reference to Other Sections: Refer to Sections 8, 12 and 13 for further information.

7. HANDLING AND STORAGE

Precautions for Safe Handling: Handle in accordance with product label and/or product insert information. Handle in accordance with good industrial hygiene and safety practices.

Conditions for Safe Storage, Including Any Incompatibilities: Store at 15° to 30°C (59° to 86°F) Shake well before use. Store according to label and/or product insert information.

Specific End Use: Pharmaceutical drug product.

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8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Occupational Exposure Guidelines:

Ingredient	Type	Value
Lidocaine Hydrochloride	Not established	Not established

Engineering Controls:

Engineering controls should be used as the primary means to control exposures.

Respiratory Protection:

Respiratory protection is normally not required during intended product use. Where respirators are deemed necessary to reduce or control occupational exposures, use NIOSH-approved respiratory protection and have an effective respirator program in place (applicable U.S. regulation OSHA 29 CFR 1910.134).

Eyes Protection:

Eye protection is normally not required during intended product use. Face shields or goggles may be required if splash potential exists or if corrosive materials are present. Approved eye protection (e.g., bearing the ANSI Z87 or CSA stamp) is preferred. Maintain eyewash facilities in the work area.

Hand Protection:

Chemically compatible gloves are recommended. For handling solutions, ensure that the glove material is protective against the solvent being used. Use handling practices that minimize direct hand contact. Employees who are sensitive to natural rubber (latex) should use nitrile or other synthetic non-latex gloves. Use of powdered latex gloves should be avoided due to the risk of latex allergy.

Skin Protection:

Wear protective laboratory coat, apron, or disposable garment when working with large quantities.

General Hygiene Considerations:

Always observe good personal hygiene measures, such as washing after handling the material and before eating, drinking, and/or smoking. Routinely wash work clothing and protective equipment to remove contaminants.

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9. PHYSICAL AND CHEMICAL PROPERTIES

Physical State/Color:	Clear, viscous solution.
Odor:	No data available.
Odor Threshold:	No data available.
pH:	5.0 to 7.0.
Melting Point:	No data available.
Freezing Point:	No data available.
Boiling Point:	No data available.
Flash Point:	>150°F.
Evaporation Rate:	No data available.
Flammability (solid, gas):	No data available.
Flammability Limit - Lower:	No data available.
Flammability Limit - Upper:	No data available.
Vapor Pressure:	No data available.
Vapor Density:	>1.
Relative Density:	Approximately that of water.
Solubility(ies):	Very soluble in water and alcohol; soluble in chloroform; insoluble in ether.
Partition Coefficient (n-octanol/water):	No data available.
Auto-Ignition Temperature:	No data available.
Decomposition Temperature:	No data available.
Viscosity:	No data available.

10. STABILITY AND REACTIVITY

Reactivity:	The product is stable and non-reactive under normal conditions of use, storage and transport.
Chemical Stability:	Stable under recommended storage conditions.
Possibility of Hazardous Reactions:	No data available.
Conditions to Avoid (e.g., static discharge, shock, or vibration):	Contact with incompatible materials.
Incompatible Materials:	Strongly alkaline conditions. Methyl vinyl ether; zinc.
Hazardous Decomposition Products:	During thermal decomposition, it may be possible to generate irritating vapors and/or toxic fumes of carbon oxides (COx), nitrogen oxides (NOx), and hydrogen chloride.

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11. TOXICOLOGICAL INFORMATION

Information on the Likely Routes of Exposure

Inhalation: No data available.

Ingestion: Harmful if swallowed.

Skin Contact: No data available.

Eye Contact: No data available.

Symptoms Related to the Physical, Chemical and Toxicological Characteristics:

See Section 4. To the best of our knowledge, the chemical, physical and toxicological properties have not been thoroughly investigated.

Delayed and Immediate Effects of Exposure:

No data available.

Acute Toxicity

Not fully established. This product is a mixture that has not been fully tested as a whole. Information provided herein is derived from the approved product insert and/or supplier SDS for active ingredients.

Ingredient	Species	Route	Test Type	Dosage
Lidocaine Hydrochloride	Mouse	Oral	LD ₅₀	292 mg/kg
Lidocaine Hydrochloride	Rat	Oral	LD ₅₀	159-324 mg/kg

Irritation / Sensitization

Ingredient	Study Type	Species	Severity
No data available	No data available	No data available	No data available

Repeated Dose Toxicity

Ingredient	Duration	Species	Route	Dosage	Test Type	Target Organ
No data available	No data available	No data available	No data available	No data available	No data available	No data available

Reproduction and Developmental Toxicity

Ingredient	Study Type	Species	Route	Dosage	Test Type	Effect(s)
No data available	No data available	No data available	No data available	No data available	No data available	No data available

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Genetic Toxicity

Ingredient	Study Type	Cell Type / Organism	Result
Lidocaine Hydrochloride	Ames Test	S. typhimurium and E. coli	Negative
Lidocaine Hydrochloride	Chromosomal aberration assay	Human lymphocytes	Negative
Lidocaine Hydrochloride	<i>In Vivo</i> micronucleus assay	Mouse	Negative

Aspiration Hazard:	None anticipated from normal handling of this product.
Toxicokinetics/Metabolism:	See package insert for more information.
Target Organ Effects:	Based on clinical use, possible target organs include the nervous system and cardiovascular system.
Reproductive Effects:	Pregnancy Category B. Reproduction studies have been performed in rats at doses up to 6.6 times the human dose and have revealed no evidence of harm to the fetus caused by lidocaine.
Carcinogenicity:	Studies of lidocaine in animals to evaluate the carcinogenic potential have not been conducted.
National Toxicology Program (NTP):	Not considered to be a carcinogen.
International Agency for Research on Cancer (IARC):	Not considered to be a carcinogen.
Occupational Safety and Health Administration (OSHA):	Not considered to be a carcinogen.

12. ECOLOGICAL INFORMATION

Aquatic Toxicity

Ingredient	Species	Test Type	Dosage	Duration
Lidocaine Hydrochloride	Daphnia magna	EC ₅₀	112 mg/l	48 hours
Lidocaine Hydrochloride	Zebra danio (Danio rerio)	LC ₅₀	106 mg/l	96 hours

Terrestrial Toxicity:	No data available.
Persistence and Degradability:	No data available.
Bioaccumulative Potential:	No data available.
Mobility in Soil:	No data available.
Mobility in Environment:	No data available.
Other Adverse Effects:	No data available.

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13. DISPOSAL CONSIDERATIONS

Dispose of all waste in accordance with Federal, State and Local regulations.

14. TRANSPORT INFORMATION

Department of Transportation (DOT): Not regulated as a hazardous material.

UN Proper Shipping Name	UN Number	Transport Hazard Class	Packing Group
Not applicable	Not applicable	Not Applicable	Not applicable

International Air Transport Association (IATA): Not regulated as a dangerous good.

UN Proper Shipping Name	UN Number	Transport Hazard Class	Packing Group
Not applicable	Not applicable	Not Applicable	Not applicable

International Maritime Dangerous Good (IMDG): Not regulated as a dangerous good.

UN Proper Shipping Name	UN Number	Transport Hazard Class	Packing Group
Not applicable	Not applicable	Not Applicable	Not applicable

15. REGULATORY INFORMATION

US FEDERAL REGULATIONS

Toxic Substance Control Act (TSCA):

Ingredient	Inventory
Lidocaine Hydrochloride	No

CERCLA Hazardous Substance:

Ingredient	Reportable Quantity
Not applicable	Not applicable

EPCRA Extremely Hazardous Substances and Toxic Chemicals:

Ingredient	Section 302	Section 313
Not applicable	Not applicable	Not applicable

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U.S. STATE RIGHT-TO-KNOW REGULATIONS

Ingredient	New Jersey	Pennsylvania	Massachusetts
Lidocaine Hydrochloride	Listed	Listed	Not Listed

California Proposition 65:

This product does not contain any chemicals known to State of California to cause cancer, birth defects, or any other reproductive harm.

16. OTHER INFORMATION

See footer of this document for Revision Date and Revision Number.

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